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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BAKER BOTTS, LLP
910 LOUISIANA
HOUSTON, TX 77002-4995

EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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02/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

debbie.allen@bakerbotts.com

Office Action Summary

Application No.

10/749,296

Applicant(s)

BEHAGUE ET AL.

Examiner

Paula L. Craig

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,11-15 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,11 and 13-15 is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed November 21, 2007 with respect to Claims 21-33 have been considered but are moot in view of the new grounds of rejection.

Claim Objections

3. Claims 12 and 26 are objected to because of the following informalities: In Claim 12, "the connector" lacks antecedent basis. In Claim 26, line 3, "the housing" should be "the tubular housing". In Claim 26, line 5, "the housing" should be "the lateral U-shaped housing". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 21-24, 28, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,387,187 to Fell et al. in view of U.S. Patent No. 4,824,339 to Bainbridge et al.

6. For Claim 21, Fell teaches a bag system including a collection machine with a peristaltic pump (pumps P1, P2, P3, P101, and P102, Abstract, Figs. 1-2, col. 2, lines 18-36, col. 4, lines 7-49). A collection device 22 is operable to collect a biological fluid (Figs. 1-2, col. 2, lines 18-68, col. 4, lines 7-52). Fell teaches a solution bag 18 or 118 containing an anticoagulant (Figs. 1-2, col. 2, line 28 to col. 3, line 6, col. 4, lines 7-20, col. 7, lines 7-49). A collection bag 26 is operable to receive the biological fluid collected and the anticoagulant (Figs. 1-2, col. 2, line 18 to col. 5, line 25). A first flexible tube provides fluid communication between the collection device 22 and the collection bag 26 (a portion of tubing 20 runs directly from needle 22 to collection bag 26 through Y-connector 34; Figs. 1-2, col. 2, lines 18-68). A second flexible tube provides fluid communication between the solution bag 18 or 118 and the collection bag 26 (a portion of tubing 20 connects bags 18 or 118 and collection bag 26, either through Y-connector 34 or through valve V102; Figs. 1-2, col. 2, line 18 to col. 3, line 6, col. 4, lines 7-24). Fell teaches a connector connecting the first and second flexible tubes (Y-connector 34 and valve V102 each connect the portions of tubing 20, Figs. 1-2, col. 2, line 18 to col. 3, line 6, col. 4, lines 7-24). Fell teaches a loop formed entirely from the

second flexible tube, with the loop having a conformation operable to allow its disposition around a head of the peristaltic pump (the portion of tubing 20 between solution bags 18 or 118 and collection bag 26 loops around pump P3 or pump P101; Figs. 1-2, col. 2, line 18 to col. 3, line 6, col. 4, lines 7-24). Fell teaches the system having a closed circuit (Figs. 1-2, col. 2, line 18 to col. 6, line 27). Fell does not expressly teach an association device operable to form the loop. However, association devices to form loops for use with peristaltic pumps are well known in the art.

Bainbridge confirms this and teaches a peristaltic pump cartridge for use with a bag system (Abstract, Figs. 1-7, col. 1, lines 5-16, col. 2, lines 30-61). Bainbridge teaches a first flexible tube 40 and a second flexible tube 38 (Figs. 1-6, col. 2, lines 32-61; note tube 40 is for blood inflow, while tube 38 leads to a bag of anticoagulant). Bainbridge teaches a variety of loop configurations for disposition around the heads of peristaltic pumps, and teaches that the loop configuration depends on the flow direction desired and the configuration of the pump (Figs. 1-6, col. 1, lines 42-68; col. 2, line 31 to col. 3, line 13; note the loops in tubes 40, 38, 58, and 56). Bainbridge teaches a connector connecting the first and second flexible tubes and an association device fully operable to form a loop entirely from the second flexible tube 38, with the loop located between the association device and the connector (connector includes the slot 48 in top wall 50 holding tube 38, as well as one of the supports 46; association device includes the slot 48 in bottom wall 52 holding tube 38, as well as another one of the supports 46; Figs. 1-6, col. 2, lines 32-61). Bainbridge teaches that the association device maintains the loops in their aligned positions against the pump rollers (col. 4, lines 5-6). In light of

Fell's teaching of a loop, it would have been obvious to one of ordinary skill in the art to modify Fell to include an association device operable to form the loop, with the loop located between an association device and a connector, as taught by Bainbridge, to maintain the loops in their aligned positions against the pump rollers, as taught by Bainbridge.

7. For Claim 22, Fell teaches a three way connector to which a downstream end of an upstream part of the first tube, an upstream end of the downstream part of the first tube, and a downstream end of a second tube are connected (Y-connector 34 and valve V102 are each three way connectors, to which all parts of tubing 20 are connected; Figs. 1-2, col. 2, lines 45-56, col. 4, lines 7-38).

8. For Claim 23, Fell teaches a loop (Figs. 1-2, col. 2, line 18 to col. 3, line 6, col. 4, lines 7-24). Fell does not expressly teach an association device operable to allow fixation of the loop. However, association devices operable to allow fixation of loops for disposition around the heads of peristaltic pumps are well known in the art. Bainbridge confirms this and teaches an association device operable to allow fixation of a loop (col. 1, lines 42-68; col. 2, line 31 to col. 3, line 13; note the loops in tubes 40, 38, 58, and 56). Bainbridge teaches that the association device maintains the loops in their aligned positions against the pump rollers (col. 4, lines 5-6). In light of Fell's teaching of a loop, it would have been obvious to one of ordinary skill in the art to modify Fell to include an association device operable to allow fixation of the loop, as taught by Bainbridge, to maintain the loop in an aligned position against the pump rollers, as taught by Bainbridge.

9. For Claim 24, Fell does not expressly teach an association device. However, association devices operable to associate tubes are well known in the art. Bainbridge confirms this and teaches an association device with an object operable to associate first and second tubes on the device (col. 1, lines 42-68; col. 2, line 31 to col. 3, line 13; note the loops in tubes 40, 38, 58, and 56). Bainbridge teaches that the association device maintains the loops in their aligned positions against the pump rollers (col. 4, lines 5-6). In light of Fell's teaching of a loop, it would have been obvious to one of ordinary skill in the art to modify Fell to include an association device with an object operable to associate the device on the first and second tubes, as taught by Bainbridge, to maintain the loop in an aligned position against the pump rollers, as taught by Bainbridge.

10. For Claim 28, Fell teaches a subsystem including at least one satellite bag, at least one filter, and a third tube providing fluid communication between the satellite bag and the collection bag (satellite bags are containers 12, 14, 24, and 44; filters include F2, F3, F101, and bowl 10; Figs. 1-2, col. 2, line 18 to col. 4, line 37).

11. For Claim 30, Fell teaches a circuit opener V101 disposed near an upstream end of the second tube (Fig. 2, col. 4, lines 8-68).

12. For Claim 31, Fell does not teach the length of the first tube between the connector and an inlet orifice of the collection bag being greater than 15 cm. The length of the blood tubing is a result effective variable, since it affects where the donor may be placed with respect to the system. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and*

Slaney, 205 USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art to provide a suitable length of tubing to reach the donor.

13. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of Bainbridge and further in view of Poulsen (5,309,604).

14. For Claim 25, Fell/Bainbridge teach all the limitations of Claim 21, as described above in paragraph 6. Fell does not teach an association device. Poulsen teaches an association device for holding loops of medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). Poulsen teaches one of the tubes being nonreversibly held in place (by passing through bore 30, Figs. 1-6 and col. 3, line 63 to col. 4, line 3). Poulsen teaches another tube being reversibly held in place (by means of the first and second C-clips, Figs. 1-6 and col. 4, lines 4-42). In light of Fell's teaching of a loop, it would have been obvious to one skilled in the art to modify Fell to include an association device nonreversibly associating the device on one of the tubes and reversibly associating the device on one of the tubes, as taught by Poulsen, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

15. For Claim 26, Fell does not teach an association device. Poulsen teaches an association device for holding loops of medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). Poulsen teaches the association device having a piece with a tubular housing operable to receive a tube by inserting the tube into the housing (bore 30, Figs. 1-6 and col. 3, line 63 to col. 4, line

3). Poulsen teaches a lateral U-shaped housing operable to receive another tube by snapping the tube into the housing (first C-clip, Figs. 1-6 and col. 4, lines 4-29). It would have been obvious to modify Fell to include an association device having a piece with a tubular housing forming an object operable to receive a tube by inserting the tube into the housing, and a lateral U-shaped housing operable to receive another tube by snapping the tube into the housing, as taught by Poulsen, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

16. For Claim 27, Fell does not teach an association device. Poulsen teaches an association device with a lateral U-shaped housing (first C-clip, Figs. 1-6 and col. 4, lines 4-29). Poulsen teaches the use of the association device for holding loops of medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). It would have been obvious to one of ordinary skill in the art to modify Fell to include using the association device of Poulsen at any point where trailing or untidy tubes were a problem, such as the downstream part of the first tube, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

17. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of Bainbridge and further in view of Becker (4,558,996).

18. For Claim 29, Fell/Bainbridge teach all the limitations of Claim 21, as described above in paragraph 6. Fell does not expressly teach the piece being molded from a sterilizable plastics material. However, the use of sterilizable plastics material in bag systems is well known in the art. Applicant's specification indicates that polycarbonate

is a suitable sterilizable plastic material (page 11, lines 11-12). Becker teaches an association device molded from polycarbonate (Fig. 6, col. 5, lines 39-46, and Claim 21). It would have been obvious to one of ordinary skill in the art to modify Fell to include the association device being molded from a sterilizable plastics material, as taught by Becker.

19. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of Bainbridge and further in view of Tamari (5,215,450).

20. For Claim 32, Fell/Bainbridge teach all the limitations of Claim 21, as described above in paragraph 6. Fell does not teach a part of the second tube forming the loop having a hardness less than that of the first tube. However, it is well known in the art of peristaltic pumps to have part or all of the tubing in the area of the pump have a hardness less than that of other tubes in the system. Tamari teaches a peristaltic pump for use with blood, with a peristaltic pump tube having a part with a hardness less than that of other tubes in the system (thin wall section has a hardness less than other tubes in the system, Figs. 2a-8b, Abstract, col. 25, lines 5-8). Tamari teaches that the thin wall tubing in the area of the pump decreases the torque required to squeeze the tubing and extends tubing pumping life (col. 17, lines 46-68, col. 22, lines 42-45). It would have been obvious to one of ordinary skill in the art to modify Fell to include a part of the second tube forming the loop having a hardness less than that of the first tube, as taught by Tamari, to decrease the torque required to squeeze the tubing and extend tubing pumping life, as taught by Tamari.

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of Bainbridge and further in view of Gilcher (6,113,554).

22. For Claim 33, Fell/Bainbridge teach all the limitations of Claim 21, as described above in paragraph 6. Fell does not teach a subsystem operable to allow sampling of the biological fluid. However, subsystems for sampling are well known in the art.

Gilcher '554 teaches a bag system with a collection machine including a peristaltic pump, a solution bag, a collection bag, first and second flexible tubes, an association device, and a closed circuit (Figs. 1, 3, 4, and 5 and col. 3, lines 26-67). Gilcher '554 teaches a subsystem operable to allow sampling of the biological fluid disposed on the first tube upstream of the connector (pre-sample pouch 168 and tube 166, Figs. 1 and 4 and col. 6, lines 15-26). Gilcher '554 teaches that the sampling subsystem allows for collection of a sample of a donor's blood without a separate venipuncture (col. 6, lines 15-21). Gilcher '554 teaches that the features of Fell, which is U.S. Patent No. 5,387,187, may be used (col. 12, lines 9-23). It would have been obvious to one of ordinary skill in the art to modify Fell to include a subsystem to allow sampling of the biological fluid disposed on the first tube upstream of the connector, as taught by Gilcher '554, to allow for collection of a sample of a donor's blood without a separate venipuncture, as taught by Gilcher '554.

Allowable Subject Matter

23. Claims 1, 4, 11, and 13-15 are allowed. The following is an examiner's statement of reasons for allowance: The closest prior art is U.S. Patent Nos. 4,379,452 to DeVries, 4,824,339 to Bainbridge et al., 4,823,833 to Hogan et al., 5,309,604 to Poulsen, 4,385,630 to Gilcher et al., 5,868,696 to Giesler et al., and 5,352,371 to Felt. DeVries teaches a closed circuit bag system with a collection machine, a peristaltic pump, a collection device operable to collect a biological fluid, a solution bag, first and second flexible tubes, a five-way junction, and a loop around the head of a peristaltic pump, but does not teach the loop being between a Y-junction and an I junction of the five-way junction. Bainbridge teaches an peristaltic pump system for a blood processing device including tubing, a solution bag, and a five-way association device, but does not teach a collection device, a collection bag, the association device being a five-way junction, nor a loop between a Y junction and an I junction of a five-way junction. Hogan teaches a closed circuit bag system with a peristaltic pump, a five-way junction including a Y junction and an I junction, and tubing forming a loop about the head of a peristaltic pump, but does not teach a collection device operable to collect a biological fluid, a solution bag containing an anticoagulant or preservation solution, or a loop between the Y junction and the I junction. Poulsen teaches a 4-way association device for tubing loops including an I junction, but does not teach the other limitations. Gilcher '630 teaches most of the claimed limitations, but does not teach a five-way junction, nor a loop between a Y junction and an I junction of a five-way junction. Giesler '696 teaches a closed circuit bag system with a collection machine, a peristaltic

pump, a collection device, solution and collection bags, first and second flexible tubes, and a five-way junction, but does not teach a loop between a Y junction and an I junction of a five-way junction. Felt '371 teaches a closed circuit bag system with two bags, two tubes, a peristaltic pump, a five-way junction including a Y junction, and an I junction, but does not teach the I junction being part of the five-way junction, does not teach a loop between the Y junction and the I junction, and does not expressly teach a loop disposed around the head of the peristaltic pump. Combining the features of the references would not produce the claimed invention; in addition, motivation is lacking to combine the features of the various references.

24. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal stroke extending to the right.